

dosage, based upon wholesalers' price lists, with the AWP reported by Baxter in the 2001 *Red Book*.

<b>Drug in Lowest Dosage Form</b>	<b>Baxter's 2001 Red Book AWP</b>	<b>DOJ Determined Actual AWP</b>	<b>Difference</b>	<b>Percentage Spread</b>
Dextrose	\$928.51	\$2.25	\$926.26	41,167%
Dextrose Sodium Chloride	\$357.69	\$2.93	\$354.76	12,108%
Sodium Chloride	\$928.51	\$1.71	\$926.80	54,199%
Factor VIII	\$1.28	\$.92	\$.36	39%

(P006299-006316).

#### **6. Evidence Concerning Gammagard S/D (immune globulin solution)**

294. Baxter admittedly manipulated the AWP for Gammagard S/D. In 1996, Baxter distributed a memo providing “[t]he deliberate manipulation of AWP or WAC prices is a problem that we need to address. The spread between acquisition cost and AWP/WAC is a direct profit for customers, and is being used to increase product positioning in the market by certain manufacturers.” Immediately below this text is a handwritten note reading “[w]ill raise AWP for GG/SD by 15%.” (BAX MDL 0012778) (Highly Confidential).

295. According to Baxter's own documents, the published AWPs for Gammagard S/D were higher than the actual prices provided to wholesalers. In a customer announcement dated September 24, 1996, Baxter increased the AWP for one particular dosage of Gammagard S/D from \$640.71 to \$737.00, and the WAC from \$365.00 to \$420.00. The difference between the new AWP and the new WAC (\$317.00) constituted a 43% spread. (BAX MDL 005366) (Highly Confidential).

#### **7. Inflated AWPs From Baxter's Price Lists**

296. In response to government subpoenas, Baxter produced numerous price lists setting forth spreads between AWPs and prices apparently offered to wholesalers, providers and other intermediaries. A review of those price lists reveals that Baxter has consistently offered hundreds of its drugs and other solutions to its customers at prices significantly below the

published AWP and that the spread was of great importance to its customers. To repeat every one of those drugs and the spread offered to each specific customer here is not practical. However, set forth below in Tables 1 and 2 are a number of those drugs (not already referenced above) with spreads between the AWPs and direct prices. Table 1 is an analysis of certain dosages of Baxter drugs from a document entitled "Baxter Healthcare Corporation Intravenous and Irrigation Solution Products Report" (BAX MDL 0003428-46) (Highly Confidential)).

**Table 1**

<b>Drug</b>	<b>AWP</b>	<b>DP</b>	<b>Difference</b>	<b>% Spread</b>
Ringers	10.84	6.34	4.50	71%
Lactated Ringers	12.36	7.43	4.93	66%
Plasma-Lyte 148	15.67	10.85	4.82	44%
5% Travert and electrolyte no. 2	16.39	11.30	5.09	45%
6% GENTRAN75	73.46	33.19	40.27	121%
Sterile Water	9.97	6.15	3.82	62%
Sodium Lactate	17.98	11.11	6.87	62%
Osmotrol	70.28	35.12	35.16	100%
Gentamycin	10.78	7.25	3.53	49%
Metronidazole injection	15.34	7.85	7.49	95%
Rocephin	40.18	32.67	7.51	23%
Nitroglycerin	17.37	9.82	7.55	77%
Potassium Chloride Injection	14.63	10.16	4.47	44%
Dopamine	19.30	13.40	5.90	44%
Lidocaine	22.74	13.48	9.26	67%
Heparin	9.94	6.49	3.45	53%
Theophylline	11.45	7.81	3.64	47%
Glycine for Irrigation	32.87	19.70	13.17	67%
Tis-U-Sol	22.73	11.36	11.37	100%
Acetic Acid	20.70	10.91	9.79	90%
Irrigating Solution G	16.67	11.04	5.63	51%
Balanced Salt Solution	28.76	15.00	13.76	92%
Sodium Bicarbonate	39.23	16.36	22.87	140%

297. Table 2 is an analysis of certain dosages of Baxter drugs from a document entitled "IV Nutrition Products" (BAX MDL 0003421-26) (Highly Confidential).

**Table 2**

<b>Drug</b>	<b>AWP</b>	<b>DP</b>	<b>Difference</b>	<b>% Spread</b>
Novamine Injection	95.14	51.48	43.66	85%
Travasol	83.44	40.21	43.23	108%
RenAmin Injection	75.00	48.00	27.00	56%

Aminess Essential Amino Acid	107.35	66.00	41.35	63%
BranchAmin Injection	93.60	60.00	33.60	56%

#### **8. Baxter Provided Free Goods and Other Incentives**

13. Baxter also provided physicians with free goods with the understanding that physicians would bill for those goods, in violation of federal law. Billing for free goods was a way for physicians to obtain greater profit at the expense of the Class. Baxter's fraudulent use of free goods aimed at increasing market share is evidenced by an internal memorandum from a Baxter contract administrator to certain field sales managers encouraging the distribution by U.S. mail or otherwise of free product to achieve overall price reduction:

BAXTER: "The attached notice from Quantum Headquarters was sent on April 10th to all their centers regarding the reduction on Recombinate pricing. Please note that they want to continue to be invoiced at the \$.81 price. They have requested that we send them free product every quarter calculated by looking at the number of units purchased in that quarter and the \$.13 reduction in price . . . free product given to achieve overall price reduction."

Letter from Stark, Committee on Ways and Means to Holman, Pres. Pharmaceutical Research and Manufacturers of America, Sept. 28, 2002 (P0075410-44).

298. As set forth above, Baxter's scheme to inflate its reported AWPs, market the resulting spread, and channel to providers "free" goods – all in order to increase the market share of its drugs – has resulted in excessive overpayments by Plaintiffs and the Class.

#### **F. Bayer**

299. Bayer engages in an organization-wide and deliberate scheme to inflate AWPs. Bayer has stated fraudulent AWPs for all or almost all of its drugs, including those set forth below. The specific drugs of Bayer for which relief is sought in this case are set forth in Appendix A, and are set forth below:

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
BAYER	Cipro	ciprofloxacin or ciprofloxacin hcl	Antibiotic Agent (Anti-Infective Agent) Used in the treatment of various bacterial infections, including anthrax
	Cipro XR	ciprofloxacin hcl-ciprofloxacin betaine	Antibiotic Agent (Anti-Infective Agent) Used in the treatment of various bacterial infections, including anthrax
	DTIC-Dome	dacarbazine	Antineoplastic Used in the treatment of melanoma and Hodgkin's disease
	Gamimune N	immune globulin (human) iv	Immunizing Agent Used as maintenance therapy in patients with compromised immune systems
	Koate-HP	antihemophilic factor (human)	Antihemophilic Factor (Blood Modifier) Used to increase blood clotting and decrease bleeding episodes
	Kogenate	antihemophilic factor (recombinant)	Antihemophilic Factor (Blood Modifier) Used to increase blood clotting and decrease bleeding episodes
	Mithracin	plicamycin	Antineoplastic; Antihypercalcemic Agent Used in the treatment of various forms of cancer

### 1. Bayer Has Been the Target of Government Investigations

300. In connection with its scheme to inflate AWPs, Bayer has been investigated by the Department of Justice, Department of Health and Human Services, Office of Inspector General, and the Commonwealth of Massachusetts. Bayer agreed to settle claims asserted by the United States government and 47 states arising from its fraudulent pricing and marketing practices. According to the DOJ's January 23, 2001 press release:

The government's investigation of the allegations...revealed that [Bayer] beginning in the early 1990s, falsely inflated the reported drug prices – referred to by the industry as the Average Wholesale Price (AWP), the Direct Price and the Wholesale Acquisition Cost – used by state governments to set reimbursement rates for the Medicaid program. By setting an extremely high AWP and, subsequently, selling drugs at a dramatic discount, Bayer induced physicians to purchase its products rather than those of competitors by enabling doctors to profit tremendously from reimbursement paid to them by the government.

The Bayer AWPs at issue in the investigation involved Bayer's biologic products such as Kogenate, Koate-HP, and Gamimmune, which are widely used in treating hemophilia and immune deficiency diseases. The investigation further revealed that the practice in which Bayer selectively engaged, commonly referred to as "marketing the spread," also had the effect of causing other drug companies to inflate their AWPs.

"Bayer Corporation Settlement on Medicaid Drug Pries" (P011236-011237).

301. As part of its settlement of government claims in 2000, Bayer is required, under the terms of a corporate integrity agreement, to provide state governments and the federal government with the average selling prices of its drugs – a price which accounts for all discounts, free samples, rebates and all other price concessions provided by Bayer to any relevant purchaser that result in a reduction of the ultimate cost to Bayer's customers.

302. In April 2003, Bayer also agreed to pay the government \$251.6 million in civil penalties for violating the Federal Prescription Drug Marketing Act for alleged overcharges involving its antibiotic Cipro and its high blood pressure drug Adalat.

## **2. Bayer Controls the Published AWP for Its Products**

303. Bayer has controlled and set the AWPs for its pharmaceutical products through direct communications with industry compendia during the Class Period. In one internal marketing memorandum, Bayer stated:

I would like to formally request that you contact Redbook and request an AWP change for all sizes (670-20, 670-30, 670-50) of Kogenate from \$1.18 per IU to \$1.24 per IU to match Baxter's increase. I have attached a letter from Baxter to Redbook outlining their price change request. (Prior to making the change in AWP for Kogenate, please confirm with Redbook that Baxter has indeed initiated a price change.)

(BAY005278) (Highly Confidential).

## **3. Bayer's AWP Manipulation Benefited Providers at the Expense of the Class**

304. As detailed in a September 28, 2000 letter from Representative Stark to Alan F. Holmer, President of the Pharmaceutical Research and Manufacturers of America, internal Bayer

documents reveal Bayer knowingly participated and directed the scheme to artificially inflate the AWPs for its products and to market the spread:

BAYER: "Chris, if Baxter has increased their AWP then we must do the same. Many of the Homecare companies are paid based on a discount from AWP. If we are lowed [sic] than Baxter then the return will be lower to the HHC. It is a very simple process to increase our AWP, and can be done overnight."

(P007549.)

305. Tom Bliley, in a letter dated September 25, 2000 to the Health Care Financing Administration, analyzed drug sales in Florida and noted that sales of Bayer's WhinRho "skyrocketed" when competitors reduced their spreads but Bayer did not.

#### **4. Specific Bayer AWPs Documented by the DOJ**

306. In a report published by the DHHS, the DOJ documented at least 10 instances where the published AWPs for various dosages of two drugs manufactured by Bayer were substantially higher than the actual prices listed by wholesalers. The chart below sets forth the two drugs identified by the DOJ and the spread associated with one particular dosage of each drug. These figures compare the DOJ's determination of an accurate AWP for that particular dosage, based upon wholesalers' price lists, with the AWP reported by Abbott in the 2001 *Red Book*.

Drug	Bayer's 2001 Red Book AWP	DOJ Determined Actual AWP	Difference	Percentage Spread
Immune Globulin	\$450.00	\$362.50	\$87.50	24%
Factor VIII	\$0.92	\$0.42	\$0.50	119%

(AB-00-86 (P006299-006316)).

307. In a DHHS OIG report (*see* OEI-03-00-00310 (P006398-006424)), the government also discovered that the AWP for all immune globulin pharmaceuticals (of a dosage of 5g), including Bayer's Gamimune® (Bayer was one of five manufacturers of the dosage listed in the 1997 *Red Book*), were over inflated by an average spread of 32.21%.

308. According to the government's settlement with Bayer arising out of Bayer's fraudulent pricing and marketing practices, the Bayer AWPs at issue in the investigation (and ultimately settled) include the AWPs for Kogenate.

**5. Inflated AWPs From Bayer's Price Lists**

309. According to Bayer's own documents, the published AWPs for its drugs were higher than the actual prices provided to wholesalers. In response to government subpoenas, Bayer produced numerous price lists setting forth spreads between AWPs and prices apparently offered to wholesalers, providers and other intermediaries. A review of those price lists reveals that Bayer has consistently offered hundreds of its drugs and other solutions to its customers at prices significantly below the published AWP and that the spread was of great importance to its customers.

**6. Bayer Provided Free Goods and Other Incentives**

310. In addition to marketing the spread, Bayer has utilized other impermissible inducements to stimulate sales of its drugs. These inducements were designed to result in a lower net cost to the provider while concealing the actual wholesale price beneath a high invoice price. By utilizing "off-invoice" inducements, Bayer provided purchasers with substantial discounts meant to gain their patronage while maintaining the fiction of a higher wholesale price.

311. Evidence of these practices is found in an October 1, 1996 Bayer internal memorandum addressing volume sales opportunities for the pharmaceutical Kogenate®:

BAYER: "I have been told that our present Kogenate price, \$.66 is the highest price that Quantum is paying for recombinant factor VIII. In order to sell the additional 12mm/u we will need a lower price. I suggest a price of \$.60 to \$.62 to secure this volume. From Quantum's stand [sic] point, a price off invoice, is the most desirable. We could calculate our offer in the form of a marketing grant, a special educational grant, payment for specific data gathering regarding Hemophilia treatment, or anything else that will produce the same dollar benefit to Quantum Health Resources."

312. As set forth above, Bayer's scheme to inflate its reported AWPs and market the resulting spread to increase the market share of its drugs and its use of other "off invoice" rebates and financial inducements to its customers has resulted in excessive overpayments by Plaintiffs and the Class.

313. Bayer routinely offered its customers off-invoice discounts as one feature of its standard contracts. (BAYM002428).

#### **7. Bayer Concealed Its AWP Manipulation**

314. Bayer deliberately acted to conceal its fraudulent reporting and marketing of the AWP spread. Bayer routinely required that its customers keep secret the prices they were being charged for Bayer drugs. (BAYM000913, BAYM002436).

#### **G. The BMS Group (Bristol-Myers, OTN and Apothecon)**

315. The BMS Group has engaged in an ongoing deliberate scheme to inflate AWPs. The specific drugs for which relief is sought in this case are identified in Appendix A and are as follows:

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
BMS GROUP (Bristol-Myers, OTN and Apothecon)	Avapro	irbesartan	Antihypertensive Agent Used to treat hypertension
	Blenoxane	bleomycin sulfate	Antineoplastic Used in the treatment of various forms of cancer
	Buspar	buspirone hcl	Antianxiety Agent (Psychotherapeutic Agent) Used to treat certain anxiety disorders or to relieve the symptoms of anxiety
	Carboplatin	paraplatin	Antineoplastic Used to treat cancer of the ovaries
	Cefzil	cefprozil	Antibacterial Agent (Anti-Infective Agent) Used in the treatment of infections caused by bacteria
	Coumadin	warfarin sodium	Anticoagulant (Blood Modifier) Used to promote clotting
	Cytoxan	cyclophosphamide	Antineoplastic Used in the treatment of various forms of cancer

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
	Etopophos	etoposide phosphate	Antineoplastic Used to treat cancer of the testicles and certain types of lung cancer
	Glucophage	metformin hcl	Antihyperglycemic Agent Used to treat type 2 diabetes mellitus.
	Monopril	fosinopril sodium	Antihypertensive Agent; Vasodilator (Cardiovascular Agent) Used to treat hypertension
	Monopril HCT	fosinopril sodium & hydrochlorothiazide	ACE Inhibitor (Cardiovascular Agent) Used in the treatment of hypertension and congestive heart failure
	Plavix	clopidogrel bisulfate	Antithrombotic Agent Used to lessen the chance of heart attack or stroke
	Rubex	doxorubicin hcl	Antineoplastic Used in the treatment of various forms of cancer
	Serzone	nefazodone hcl	Antidepressant (Psychotherapeutic Agent) Used to treat mental depression
	Taxol	paclitaxel	Antineoplastic Used in the treatment of various forms of cancer
	Tequin	gatifloxacin	Antibacterial Agent (Anti-Infective Agent) Used to treat bacterial infections
	Vepesid	etoposide	Antineoplastic Used to treat cancer of the testicles and certain types of lung cancer
	Videx EC	didanosine	Antiviral Agent (Anti-Infective Agent) Used in the treatment of HIV infection
		amikacin sulfate	Antibiotic Agent (Anti-Infective Agent) Used to treat respiratory tract, urinary tract, bone, skin and soft tissue infections
		amphotericin b	Antifungal Agent (Anti-Infective Agent) Used to help the body overcome serious fungus infections

### 1. The BMS Group Has Been the Target of Government Investigations

316. In connection with its scheme to inflate AWPs, BMS has been investigated by the United States Department of Justice, Commonwealth of Massachusetts, Office of Inspector General of the U.S. Department of Health and Human Services, Attorney General for the State of Texas, State of California Department of Justice Office of the Attorney General, State of California Department of Justice, Bureau of Medi-Cal Fraud and Elder Abuse, and the U.S.

House of Representatives, Committee on Commerce. Defendant Apothecon has been investigated in connection with its scheme to inflate AWPs by at least the Office of Medicare Fraud and Elder Abuse, Office of Attorney General, State of Texas.

317. These investigations confirm that BMS engaged in an ongoing deliberate scheme to inflate AWPs. For example, by letter dated February 27, 2001 to BMS, Rep. Stark outlined numerous examples of illegal practices by BMS. Referring to a letter from Denis Kaszuba, a senior pricing analyst at BMS to Medispan, dated August 10, 1992 (BMSAWP/0011247), Rep. Stark noted:

Bristol has control over the AWPs, DPs, and WACs published for its drugs and directs national publishers to change their prices. Bristol directed a national publisher of drug prices to increase all of Bristol's AWPs for oncology drugs by multiplying Bristol's supplied direct prices by a 25% factor rather than the previous 20.5% factor . . . The increase in the AWP created a spread that, in itself, provided a financial kickback to oncologists for prescribing Bristol's cancer drugs.

318. In the same letter, Rep. Stark noted:

The evidence clearly shows that Bristol has intentionally reported inflated prices and has engaged in other improper business practices in order to cause its customers to receive windfall profits from Medicare and Medicaid when submitting claims for certain drugs. The evidence further reveals that Bristol manipulated prices for the express purpose of expanding sales and increasing market share of certain drugs where the arranging of a financial benefit or inducement would influence the decisions of healthcare providers submitting the Medicare and Medicaid claims.

## 2. The BMS Group Controls the Published AWP for Its Products

319. The BMS Group has controlled and set the AWPs for its pharmaceutical products through direct communications with industry compendia during the Class Period. In one BMS document, Denise Kaszuba, a senior BMS Group pricing analyst, instructed the *Red Book* that:

Effective immediately, Bristol-Myers Oncology Division products factor used in determining the AWP should be changed from 20.5% to 25%. This change should not effect [sic] any other business unit of Bristol-Myers Squibb Company.

320. Other internal documents clearly indicate that BMS had direct control over the spread between its states wholesale price and the published AWP. A BMS office dispatch dated September 9, 1992 notes the need for a mark up of the AWP over the state wholesale price. "After reviewing the results of the wholesaler survey performed by Bristol Oncology . . we have determined that for those items with a labeler 0003, we will use a 1.25 mark-up and for those items with the labeler 00015, we will use a 1.20 mark-up. We noticed too, that FDB and Redbook use a 1.20 for everything." (BMSAWP/0011246).

**3. BMS's AWP Manipulation Benefited Providers at the Expense of the Class**

321. BMS was well aware that providers and other purchasers of its drugs were using the spread to determine whether to purchase its drugs. Indeed, BMS was aware of and tracked the prices and AWPs of its competitors in order to remain competitive. In an internal BMS memorandum, BMS identifies its competitors who sell etoposide (Gensia, Pharmacia, Abbott, Chiron, Ben Venue, Immunex and Astra) and their corresponding list price and AWPs. (BMS3CA/000128).

322. BMS created AWP competitor analyses that tracked the AWPs of its competitors' relevant drugs, and used that date internally to propose suggested AWPs for BMS drugs. One such competitor analysis set forth the competitor AWPs for Atenolol with chlorthalidone and provided an "Apothecon suggested AWP" for each dosage. (BMS3CA/000648)

323. BMS clearly believed that the maintenance of a spread on its drugs was important in gaining and maintaining market share. In an internal BMS document, concerning its drug Vepacid (etoposide), BMS noted:

The Etopophos product file is significantly superior to that of etoposide injection . . . Currently, physician practice can take advantage of the growing disparity between Vepesid's list price (and, subsequently, the Average Wholesale Price) and the actual acquisition cost when obtaining reimbursement for etoposide purchases. If the acquisition price of Etopophos is close to the list price, the physician's financial incentive for selecting the brand is largely diminished.

#### **4. Specific BMS AWPs Documented by the DOJ**

324. In a report published by the DHHS, the DOJ documented numerous instances where the published AWPs for various dosages of five (5) drugs manufactured by the BMS Group were substantially higher than the actual prices listed by wholesalers. The chart below sets forth the BMS Group drugs identified by the DOJ and the spread associated with one particular dosage of each drug. These figures compare the DOJ's determination of an accurate AWP for that particular dosage, based upon wholesalers' price lists, with the AWP reported by the BMS Group in the 2001 *Red Book*.

Drug	Manufacturer	BMS's 2001 <i>Red Book</i> AWP	DOJ Determined Actual AWP	Difference	Percentage Spread
Amikacin Sulfate	Apothecon	\$32.89	\$17.31	\$15.58	90%
Amphotericin B	Apothecon	\$17.84	\$6.20	\$11.64	188%
Bleomycin Sulfate	BMS	\$609.20	\$509.29	\$99.91	20%
Cyclophosphamide	BMS	\$102.89	\$45.83	\$57.06	125%
Etoposide (Vepesid)	BMS	\$136.49	\$34.30	\$102.19	298%

325. Other sources reveal additional evidence of fraudulent AWPs for drugs manufactured and marketed by the BMS Group:

#### **5. Other AWPs Related to VEPESID (etoposide)**

326. The February 27, 2001 letter from Rep. Stark to BMS noted that as to BMS "... the manipulated discrepancies between [BMS's] inflated AWPs and DPs versus their true costs are staggering. For example, in the 2000 edition of the *Red Book*, Bristol reported an AWP of \$1296.64 for . . . Vepesid (Etoposide) for injection . . . while Bristol was actually offering to sell the exact same drug to [a large national group purchasing organization] for \$70.00." The difference noted by Rep. Stark represents a % 1,752 spread related to Vepecid.

#### **6. Other AWPs Related to Blenoxane**

327. BMS internal documents reveal that in 1995, BMS set the *Red Book* AWP for Blenoxane at \$276.29. At the same time, BMS was selling Blenoxane to oncologists practicing in St. Petersburg, Florida for only \$224.22. In 1996, BMS increased its reported AWP for

Blenoxane to \$291.49, while continuing to sell the drug to oncologist for \$224.27. In 1997, BMS falsely reported that it had increased the AWP of Blenoxane to \$304.60, when in reality, BMS had lowered the price to oncologists to \$155.00. In 1998, BMS again reported a false AWP for Blenoxane of \$304.60 while further reducing the actual price to oncologists to \$140.00.

#### **7. The BMS Group Provided Free Goods and Other Incentives**

328. As part of its scheme the BMS Group also used free drugs and other goods to encourage participation by physicians. Thus, for example, the BMS Group provided free Etopophos® to two Miami oncologists in exchange for their agreement to purchase other BMS Group cancer drugs. Similarly, other documents show that the BMS Group provided free Cytogards in order to create a lower-than-invoice cost to physicians that purchased other cancer drugs through OTN. (A Cytogard is a device that prevents spillage of intravenous administered treatments such as BMS's cancer drug Etopophos®.)

329. As set forth above, the BMS Group's scheme to inflate its reported AWPs, market the resulting spread, and channel to providers "free" goods – all in order to increase the market share of its drugs – has resulted in excessive overpayments by Plaintiffs and the Class.

330. For example, in a report published by DHHS, the DOJ documented at least 12 instances where the published AWPs for drugs manufactured by the BMS Group were substantially higher than the actual prices listed by wholesalers.

331. The chart below sets forth five examples where the BMS Group deliberately inflated AWPs that it reported for BMS Group drugs. These figures compare the DOJ's determination of an accurate AWP, based upon wholesalers' price lists, with the AWP reported by the BMS Group in the 2001 *Red Book*.

Drug	Manufacturer	BMS's 2001 Red Book AWP	DOJ Determined Actual AWP	Difference	Percentage Spread
Amikacin Sulfate	Apothecon	\$32.89	\$17.31	\$15.58	90%
Amphotericin B	Apothecon	\$17.84	\$6.20	\$11.64	188%

Bleomycin Sulfate	BMS	\$609.20	\$509.29	\$99.91	20%
Cyclophosphamide	BMS	\$102.89	\$45.83	\$57.06	125%
Etoposide (Vepesid)	BMS	\$136.49	\$34.30	\$102.19	298%

332. In 1997, an OIG Report identified three other Medicare Part B drugs with inflated AWPs – which the 1997 *Red Book* indicates were manufactured only by the BMS Group at that time: Paraplatin® (carboplatin), Rubet® (doxorubicin hydrochloride), and Taxol® (paclitaxel). Sales of these inflated drugs were substantial. For example, Paclitaxel generated \$941 million in revenue for the BMS Group in 1997, and Carboplatin generated \$702 million in revenue in 2001.

333. The government's investigation uncovered other drugs for which the BMS Group was stating a fraudulent AWP. Specifically:

- a. In the 2000 edition of the *Red Book*, BMS reported an AWP of \$1296.64 for Vepesid (Etoposide) for injection while BMS was actually offering to sell the exact same drug to a large customer for only \$70.00.
- b. From 1995 through 1998 the *Red Book* listed AWP for BMS' Blenoxane 15u increased from \$276.29 to \$304.60, while the actual cost to physicians declined from \$224.22 to \$140.00, resulting in a spread of \$164.60 in 1998

334. An internal BMS Group document shows that the AWP set by the BMS Group for its drugs bears no relation to an *actual* wholesale price, and is greater than the highest price actually paid by providers. More specifically, in a discussion about lowering Vepesid's AWP in order to create sales for Etopophos, the BMS Group stated that the "AWP for Vepesid would be reduced from its current level to the highest bid price currently in the marketplace."

335. BMS Group documents also reveal that physicians were making medical decisions based on how much profit they could make from the AWP manipulated spread. In considering provider choice between BMS drugs Etopophos® and Vepesid® (Etoposide), the BMS Group noted that:

The Etopophos product file is significantly superior to that of etoposide injection . . . . Currently, physician practice can take advantage of the growing disparity between Vepesid's list price (and, subsequently, the Average Wholesale Price) and the actual

acquisition cost when obtaining reimbursement for etoposide purchases. If the acquisition price of Etopophos is close to the list price, the physician's financial incentive for selecting the brand is largely diminished.

336. While the BMS Group and other Defendants have placed the blame for setting published AWPs on the publications in which the AWPs are contained, another BMS Group document demonstrates that publications reporting AWPs had no discretion to set AWPs, and instead published verbatim the prices reported by the BMS Group and other Defendants. In the document, Denise Kaszuba, a senior BMS Group pricing analyst, instructed the *Red Book* that:

Effective immediately, Bristol-Myers Oncology Division products factor used in determining the AWP should be changed from 20.5% to 25%. This change should not effect [sic] any other business unit of Bristol-Myers Squibb Company.

#### H. Dey

337. Dey engages in an organization-wide and deliberate scheme to inflate AWPs. Dey has stated fraudulent AWPs for all or almost all of its drugs, including those set forth below. The specific drugs of Dey for which relief is sought in this case are set forth in Appendix A, and are identified below:

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
DEY		acetylcysteine	Mucolytic (Respiratory Agent: Diagnostic Aid) Used for certain lung conditions when increased amounts of mucus make breathing difficult
		albuterol or albuterol sulfate	Bronchodilator (Respiratory Agent) Used for relief of bronchospasm in asthma sufferers
		cromolyn sodium	Antiallergic and Mast Cell Stabilizer Used to help prevent or treat the symptoms of seasonal or chronic allergic rhinitis
		ipratropium bromide	Bronchodilator (Respiratory Agent) Used for relief of bronchospasm in asthma sufferers
		metaproterenol sulfate	Bronchodilator (Respiratory Agent) Used for relief of bronchospasm in asthma sufferers

**1. Dey Has Been the Target of Government Investigations**

338. In connection with its scheme to inflate AWPs, Dey has been investigated by the United States Department of Justice, United States Department of Health and Human Services, Office of Inspector General, the United States District Attorney for the District of Massachusetts, the Attorney General of the State of California, the Attorney General for the State of Texas, the Attorney General of the State of Connecticut, and the District Attorney for the County of Suffolk, New York State.

339. These investigations confirm that Dey has engaged in a deliberate scheme to inflate the published AWPs for many of its drugs. For instance, Dey's spread for albuterol sulfate, a drug that constituted 37 % of Dey's income in 1998, drastically increased between 1992 and 1998. In 1992, Dey's *Red Book* AWP for albuterol sulfate (.083% concentration, 3 ml) was \$32.30. McKesson's wholesale price for the drug was \$25.45 (a spread of \$ 6.85 or 27%). By 1998, Dey's *Red Book* AWP for the same concentration/dose of albuterol sulfate had barely slipped to \$30.25, while McKesson's wholesale price had plummeted to \$10.00 (a spread of \$20.25 or 202%). See September 25, 2000 letter from U.S. Rep. Bliley to Nancy-Ann Min DeParle.

340. The federal government is not the only entity to uncover Dey's scheme to inflate AWPs. The Attorneys General of Texas and West Virginia recently discovered that due to over inflated AWPs, both state's Medicaid Programs have been defrauded by Dey for millions of dollars. Texas alleges that, between 1995 and 1999, it paid \$13.7 million for Dey's albuterol sulfate and ipratropium bromide, when it should have paid only \$8.7 million – an overcharge of \$5 million. West Virginia alleges that Dey and others manipulated the AWP to significantly overcharge state agencies and residents for several drugs, including albuterol, from at least 1995 through 2000.

341. In its own suit against Dey and other pharmaceutical manufacturers for AWP manipulation, the Attorney General for the State of Connecticut documented significant spreads

between Dey's published AWPs and actual wholesale prices for many of its drugs. Incorporated below are examples cited by the Connecticut Attorney General:

Drug	NDC #	Year	AWP	ACTUAL PRICE	SPREAD	% OVERCHARGE
ALBUTEROL	49502-0303-17	1996	\$21.70	\$3.25	\$18.45	488%
IPATROPIUM BORMIDE	49502-0685-03	2001	\$44.10	\$8.35	\$35.58	355%
IPATROPIUM BROMIDE	49502-0685-03	2000	\$44.10	\$11.45	\$32.65	239%
IPATROPIUM BROMIDE	49502-0685-03	1999	\$44.10	\$11.45	\$30.11	177%

## 2. Dey Controls the Published AWP for Its Products

342. Dey has controlled and set the AWPs for its pharmaceutical products through direct communications with industry compendia during the Class Period. Dey's own documents indicate that it initially set both the AWP and WAC for its products and also regularly approved subsequent AWPs and WACs published by industry compendia. For example:

a. In a January 13, 1996 letter from Dey to First Data Bank, Day announced the availability of a new ipratropium bromide inhalation solution. The letter includes the following instructions to First Data Bank:

“Effective immediately, please update your database to reflect the introduction of this new DEY product as follows:

NDC/ Order Number	Description	Vial Size	Strength	Units per Ctn	Ctns per Case	AWP	WAC
49502-685-03	Ipatropium Bromide Inhalation Solution 2.0%	2.5ml	0.5mg/2.5ml	25	12	\$44.10	\$25.50
49502-685-60	Ipatropium Bromide Inhalation Solution 2.0%	2.5ml	0.5mg/2.5ml	60	12	\$105.60	\$60.90

(DL-CA00120) (Confidential)

b. In a 1998 worksheet produced by *Red Book* to Dey in order to verify its listings of Dey products, an employee of Dey went through each of the Dey products listed in the *Red Book* and approved each of the AWPs and WACs for each of its products. Handwritten comments on the document include the notation “9/11/98 – checked AWP & WAC pricing (backup attached)” (DL-CA 00080) (Confidential).

**3. Dey's AWP Manipulation Benefited Providers at the Expense of the Class**

343. The purpose of Dey's AWP manipulation was to increase the spread in order to maximize the profit to providers and other intermediaries. This is clear from Dey's own documents. For example:

a. Dey was aware that its customers were “spread shopping” and competed by increasing the spread to its customers. In an internal worksheet filled out by Dey in preparation for a bid of potential sales to one of its customers, Dey listed the current contract price of various products as well as a recommended new contract price. In the notes next to these figures the worksheet states, “This account needs AWP-40% or better to see profit due to the employer groups they serve. Have not made the switch to our product line due to the spread . . .” (DL-TX-0014029)

b. Competition between generic products produced by Dey was fierce and the spread was a major factor in this competition. In another similar bid price worksheet for a different customer, the corresponding notes state “cromolyn pricing is at AWP-40% and 35% respectively – bear in mind that we are competing with the branded spread and the generic perception of [sic] everything should be AWP-60%” (DL-TX-0014439)

344. This competition came at the expense of Plaintiffs and the Class whose payments were based on AWP. For instance, Albuterol sulfate, a multisource drug and one of Dey's top selling products, was a focus of the federal government's investigation into AWP inflation. OIG found that “Medicare's reimbursement amount for albuterol was nearly six times higher than the

median catalog price" and that "Medicare and its beneficiaries would save between \$226 million and \$245 million a year if albuterol were reimbursed at prices available to suppliers." See "Excessive Medicare Reimbursement for Albuterol," OEI-03-01-00410, March 2002.

345. The OIG determined that the Medicare-allowed amount for albuterol sulfate in 1996 was \$0.42. However the actual wholesale price was \$0.15, and the highest available wholesale price was \$0.21.

346. GAO also found that albuterol sulfate was one of a small number of products that accounted for a large portion of Medicare spending and volume. More specifically, albuterol sulfate ranked first in volume of units covered by Medicare, accounting for 65.8% of total units reimbursed. Furthermore, albuterol sulfate accounted for 6.3% of total Medicare spending, ranking fifth out of more than 400 covered drugs. See GAO Report to Congressional Committees, MEDICARE: Payments for Covered Outpatient Drugs Exceed Providers' Cost, Tables 1 and 2, pp. 7-8.

#### **4. Specific Dey AWPs Documented by the DOJ**

347. In a report published by the DHHS, the DOJ documented at least 15 instances where the published AWPs for various dosages of 4 drugs manufactured by Dey were substantially higher than the actual prices listed by wholesalers. The chart below sets forth the drugs identified by the DOJ and the spread associated with one particular dosage of each of the 4 drugs. These figures compare the DOJ's determination of an accurate AWP for that particular dosage, based upon wholesalers' price lists, with the AWP reported by Dey in the 2001 *Red Book*.

Drug in Lowest Dosage Form	2001 <i>Red Book</i> AWP	DOJ Determined AWP	Difference	Percentage Spread
Acetylcysteine	\$59.88	\$25.80	\$34.08	132%
Albuterol Sulfate	\$30.25	\$9.17	\$21.08	230%
Cromolyn Sodium	\$42.00	\$23.01	\$18.99	82%
Metaproterenol Sulfate	\$30.75	\$11.29	\$19.46	172%

## 5. Inflated Dey AWPs From Dey's Price Lists

348. According to Dey's own documents, the published AWPs for many of its own products were higher than the actual prices charged wholesalers and other intermediaries.

Table 1 below is excerpted from a pricing proposal by Dey to McKesson Drug Company, one of the county's largest wholesalers, dated December 20, 1995.

**Table 1**

Generic Name	Strength	Size	AWP	WAC	Suggested Sell Price	% Discount from WAC	% Spread
Acetylcysteine Solution	10%	4 mL	\$67.80	\$25.80	\$18.00	-40.0%	277%
Acetylcysteine Solution	10%	10 mL	\$40.26	\$15.27	\$13.50	-30.0%	198%
Acetylcysteine Solution	10%	30 mL	\$110.48	\$41.97	\$33.50	-35.0%	230%
Acetylcysteine Solution	20%	4 mL	\$81.36	\$31.08	\$21.50	-40.0%	278%
Acetylcysteine Solution	20%	10 mL	\$48.66	\$18.57	\$16.20	-30.0%	200%
Acetylcysteine Solution	20%	30 mL	\$133.43	\$50.64	\$39.90	-35.0%	234%
Acetylcysteine Solution	20%	100 mL	\$92.21	\$75.90	\$59.90	-40.0%	54%
Albuterol Sulfate Inhalation Soln.	0.083%	3 mL	\$30.25	\$14.50	\$12.00	-29.3%	152%
Albuterol Sulfate Inhalation Soln.	0.083%	3 mL	\$36.30	\$17.40	\$14.40	-29.3%	152%
Albuterol Sulfate Inhalation Soln.	0.083%	3 mL	\$72.60	\$34.50	\$28.80	-28.7%	152%
Cromolyn Sodium Inhalation, USP	20 mg/2ml	2 mL	\$42.00	\$34.20	\$29.00	-25.0%	45%
Cromolyn Sodium Inhalation, USP	20 mg/2ml	2 mL	\$84.00	\$66.00	\$58.00	-22.3%	45%
Metaproterenol Sulfate Inhalation Soln.	0.4%	2.5 mL	\$30.75	\$11.00	\$10.00	-21.5%	207%
Metaproterenol Sulfate Inhalation Soln.	0.6%	2.5 mL	\$30.75	\$11.00	\$10.00	-21.5%	207%
Sodium Chloride Solution	0.9%	3 mL	\$24.20	\$13.00	\$10.94	-32.7%	121%
Sodium Chloride Solution	0.9%	5mL	\$24.20	\$13.00	\$10.94	-32.7%	121%

(DL-TX 0011179)

## 6. Dey Provided Free Goods and Other Incentives

349. In addition to marketing the spread, Dey has utilized other impermissible inducements to stimulate sales of its drugs without accounting for them in its WAC or AWP. These inducements were designed to result in a lower net cost to the provider while concealing the actual wholesale price beneath a high invoice price. By utilizing "off-invoice" inducements,

Dey provided purchasers with substantial discounts meant to gain their patronage while maintaining the fiction of a higher wholesale price.

350. For example, in an announcement of a special incentive program to its customers to induce the purchase of its Ipratropium Bromide Inhalation solution, Dey sent its customers an offer sheet entitled "Profitability Enhancement For You" in which it stated "For every dollar of Dey Cromolyn Sodium unit-dose purchased, Dey will provide free goods of either: Coromolyn Sodium Inhalation Solution 0.02%, 2.5ml, at 1.0 times the rebate amount -OR- Ipatropium Bromide Inhalation Solution 0.02%, 2.5ml, when it launches, at a value of 1.5 times the rebate amount for Cromolyn." (DL-TX-0004775).

#### **7. Dey Has Concealed Its AWP Manipulation**

15. In an effort to conceal the existence of a spread from end payors, Dey concealed the true wholesale prices of its drugs. For instance, in a handwritten memorandum to Dey's pricing committee a potential pricing structure with a customer was discussed:

"I met with IPC to discuss our contract offer (illegible). . . Tom Konnelly (IPC) said he wanted to keep net pricing hidden from 3<sup>rd</sup> parties by increasing in the purchase price on our offer by 25%. IPC then requires a 25% rebate back to IPC. . . I have remarked the pricing. If this offer is accepted, the higher price will go into McKesson as a chargeback contract. Dey will then rebate IPC 25% on contract purchases on a quarterly basis. . ."

(DL-TX-0024844)

351. As set forth above, Dey's scheme to inflate its reported AWPs and market the resulting spread to increase the market share of its drugs and its use of other "off invoice" rebates and financial inducements to its customers has resulted in excessive overpayments by Plaintiffs and the Class.

#### **I. The Fujisawa Group (Fujisawa Pharmaceutical, Fujisawa Healthcare, Fujisawa USA)**

352. Fujisawa engages in an organization-wide and deliberate scheme to inflate AWPs. Fujisawa has stated fraudulent AWPs for all or almost all of its drugs, including those set forth

below. The specific drugs of Fujisawa for which relief is sought in this case are set forth in Appendix A and are identified as follows:

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
FUJISAWA GROUP (Fujisawa Healthcare, Fujisawa Pharmaceutical and Fujisawa USA)	Aristocort	triamcinolone, triamcinolone diacetate or triamcinolone acetonide	Anti-Inflammatory, Steroidal; Used in the treatment of asthma
	Aristospan	triamcinolone hexacetonide	Anti-Inflammatory Agent, Steroidal Used to provide relief for inflamed areas of the body
	Cefizox	ceftizoxime sodium or ceftizoxime in d5w	Antibiotic Agent (Anti-Infective Agent) General antibiotic
	Cyclocort	amcinonide	Anti-Inflammatory Agent Used to treat inflammatory symptoms of skin disorders
	Lyphocin	vancomycin hydrochloride	Antibacterial Agent Used to treat infections in many different parts of the body
	Nebupent	pentamidine isothionate	Antiprotozoal Agent Used to try to prevent Pneumocystis carinii pneumonia
	Pentam 300	pentamidine isethionate	Anti-Infective Agent Used in the treatment of pneumonia
	Prograf	tacrolimus	Immunosuppressant Used to lower the body's natural immunity in patients who receive organ transplants
		acyclovir sodium	Antiviral Agent Used to treat herpes simplex infections, varicella-zoster (chickenpox) in people with weakened immune systems, and severe genital herpes infections
		dexamethasone sodium phosphate	Anti-Inflammatory Agent; Antiemetic (Gastrointestinal Agent) Used in various applications to treat inflamed areas of the body
		doxorubicin hydrochloride	Antineoplastic Used in the treatment of ovarian cancer and AIDS-related Kaposi's sarcoma
		fluorouracil	Antineoplastic Used to treat cancer, including colon, rectum, breast, stomach, and pancreas
		gentamicin sulfate	Antibacterial Agent Used to treat serious bacterial infections

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
		vinblastine sulfate	Antineoplastic Used in the treatment of various forms of cancer, including lymphoma and breast cancer

**1. Fujisawa Has Been the Target of Government Investigations**

353. In connection with its scheme to inflate AWPs, Fujisawa has been investigated by the United States Department of Justice, the Office of Inspector General of the Department of Health and Human Services, the Attorney General for the State of Texas, and the Attorney General for the State of California.

**2. Fujisawa Controls the Published AWP for Its Products**

354. Fujisawa controlled and set the AWPs for its pharmaceutical products through direct communications with industry compendia during the Class Period. For example, on March 10, 1997, Fujisawa provided MediSpan with an updated listing of pack prices – including AWPs – for all of its products. (FJ-MDL 015152-015159).

**3. Fujisawa's AWP Manipulation Benefited Providers at the Expense of the Class**

355. The purpose of Fujisawa's manipulation was to increase the spread in order to maximize the profit to providers and other intermediaries at the expense of Plaintiffs and the Class. Fujisawa understood that providers and intermediaries sought significant AWP spreads. In a March 1995 Monthly Report, dated March 30, 1995, Fujisawa noted:

We have lost our Vanco business at Chartwell. They have recently been handed an edict to order those products with the largest spread between acquisition cost and AWP. Abbott has unbelievably high Vanco AWP. In an effort to counter this loss I suggested we look at picking up the Cefazolin business where our AWP for one gram Cefazolin is over \$8. Unfortunately our 10 gram price does not follow the same formula and is in the \$45 range while Schein is approximately \$58. We do however have a shot at Cefizox for Medicaid/Medicare patients which make up 50% of Chartwell's patients. Medicaid does not reimburse Chartwell for the Rocephin they currently use and while they will not reimburse for Cefizox either they could acquire Cefizox at a

fraction of the cost. They use \$400,000 in Rocephin annually, \$200,000 for Medicaid/Medicare patients. That works out to better than \$100K in savings for Chartwell.

(FJ-MDL 005687-88) (Confidential).

356. Fujisawa, in a conscious effort to increase the spread for providers and intermediaries, changed its AWPs and marketing practices accordingly. In a May 1995 Monthly Report, dated May 30, 1995, Fujisawa addressed its recent decision to increase its AWP for Vancomycin Hydrochloride and aggressively market the resulting spread increase:

Many thanks to Rick and Bruce for adjusting the AWP on the five gram Vanco. This should lead to more business. As I have previously reported, some companies are still using AWP for reimbursement purposes. Chartwell has been told to search for the largest spread and order accordingly. I would have liked to see us match Abbott's AWP for our complete Vanco, and Cefazolin line. I will settle for the five gram at \$1 below Abbott but that means that we still have to compete at the other end of the equation. For example, if Abbott's AWP is \$163 and their contract is \$30 and if our AWP is \$162 we will have to be at least \$29 to have the same spread. Follow?

(FY-MDL 005668-69) (Confidential).

357. In an October 5, 1993 interoffice memorandum discussing Fujisawa's communications with industry pricing compendia, Fujisawa acknowledged that the AWPs for nearly all of its products is inflated at least 33% over direct list prices:

One of the issues regarding our companies AWP listing is that the databases only use our listing as a "Suggested Manufacturers AWP". The standard wholesaler mark-up used by those databases is currently at 25% above direct list price which is our hospital list. Almost all of our products are at 33% or higher above list price.

(FJ-MDL 008346) (Confidential).

358. Further, just as Fujisawa motivates providers to administer drugs based on the AWP, Fujisawa rewards PBMs based on the degree of influence they exert to drive utilization of Fujisawa products. (FJ-MDL 010272-78) (Confidential).

#### 4. Specific Fujisawa AWPs Documented by the DOJ

359. In a report published by the DHHS (AB-00-86), the DOJ documented at least 35 instances where the published AWPs for various dosages of 6 drugs manufactured by Fujisawa were substantially higher than the actual prices listed by wholesalers. The chart below sets forth the 6 drugs identified by the DOJ and the spread associated with one particular dosage of each drug. These figures compare the DOJ's determination of an accurate AWP for that particular dosage, based upon wholesalers' price lists, with the AWP reported by Fujisawa in the 2001 *Red Book*.

<b>Drug</b>	<b>The Fujisawa Group's 2001 Red Book AWP</b>	<b>DOJ Determined Actual AWP</b>	<b>Difference</b>	<b>Percentage Spread</b>
Acyclovir Sodium	\$565.10 <sup>2</sup>	\$371.50	\$193.60	52%
Dexamethasone Sodium Phosphate	\$1.04 <sup>3</sup>	\$.66	\$.38	58%
Fluorouracil	\$2.87	\$1.20	\$1.67	139%
Gentamicin Sulfate	\$12.64 <sup>4</sup>	\$5.40	\$7.24	134%
Pentamidine Isethionate	\$98.75	\$36.00	\$62.75	174%
Vancomycin Hydrochloride	\$10.97 <sup>5</sup>	\$7.00	\$3.97	57%

(P006299-006316).

#### 5. Inflated AWPs From Fujisawa Price Lists

360. In response to government subpoenas, Fujisawa produced numerous price lists setting forth spreads between AWPs and prices offered to wholesalers, providers and other intermediaries. A review of those price lists reveals that Fujisawa has consistently offered drugs and other solutions to its customers at prices significantly below the published AWP and that the spread was of great importance to its customers. To repeat every one of those drugs and the spreads offered to each specific customer here is not practical.

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<sup>2</sup> Calculation based on the AWP listed in the 1998 *Red Book*.

<sup>3</sup> Calculation based on the AWP listed in the 1998 *Red Book*.

<sup>4</sup> Calculation based on the AWP listed in the 1998 *Red Book*.

<sup>5</sup> Calculation based on the AWP listed in the 1998 *Red Book*.

361. Set forth below in Table 1, however, are the AWP, contract prices and spread of a number of drugs (not already referenced above) included in a Fujisawa customer price list dated August 24, 1995, and their associated AWP spread. (FJ-MDL 013079-81) (Confidential).

**Table 1**

<b>Drug</b>	<b>Contract Price</b>	<b>AWP</b>	<b>\$ Diff AWP</b>	<b>% Spread</b>
Triamcinolone	\$14.33	\$17.95	\$3.62	25%
Calcium Gluconate	\$11.50	\$34.00	\$22.50	196%
Cefazolin Sodium	\$139.00	\$367.13	\$228.13	164%
Ceftizoxime Sodium	\$7.50	\$11.86	\$4.36	58%
Amcinonide	\$41.50	\$52.13	\$10.63	26%
Doxycycline Hyclate	\$15.00	\$73.75	\$58.75	392%
Fluphenazine Hydrochloride	\$24.10	\$30.25	\$6.15	25%
Folic Acid	\$7.25	\$11.85	\$4.26	63%
Levothyroxine Sodium	\$3.90	\$38.43	\$34.53	885%
Lidocaine Hydrochloride	\$17.00	\$24.50	\$7.50	44%
Magnesium Sulfate	\$22.00	\$138.25	\$116.25	528%
Mannitol	\$28.00	\$56.50	\$28.50	101%
Neostigmine Methylsulfate	\$8.20	\$89.30	\$81.10	989%
Oxytocin	\$13.50	\$24.50	\$11.00	81%
Potassium Acetate	\$92.00	\$312.40	\$220.40	240%
Potassium Chloride	\$12.25	\$30.50	\$18.25	149%
Potassium Phosphate	\$30.25	\$133.75	\$103.50	342%
Pyridoxine Hydrochloride	\$35.00	\$47.00	\$12.00	34%
Scopolamine Hydrobromide	\$22.00	\$30.00	\$8.00	36%
Selenium	\$18.25	\$195.25	\$177.00	970%

362. Set forth below in Table 2, however, are the AWP, contract prices and spread of a number of drugs (not already referenced above) included in a Fujisawa price list dated November 5, 1996, and their associated AWP spread. (FJ-MDL 008240-53) (Confidential).

**Table 2**

<b>Drug</b>	<b>Wholesaler Price</b>	<b>AWP</b>	<b>\$ Diff AWP</b>	<b>% Spread</b>
Adenocard IV	\$21.95	\$26.34	\$4.39	20%

<b>Drug</b>	<b>Wholesaler Price</b>	<b>AWP</b>	<b>\$ Diff AWP</b>	<b>% Spread</b>
Adenoscan	\$179.00	\$223.75	\$44.75	25%
Aristocort A	\$7.05	\$8.46	\$1.41	20%
Atropine Sulfate Injection	.64	\$1.12	\$.48	75%
Doxorubicin	\$12.44	\$45.50	\$33.06	266%
Furosemide	\$.74	\$.98	\$.24	32%
Hydroxyzine Hydrochloride	\$.42	\$.65	\$.23	55%
Protamine Sulfate	\$3.33	\$5.32	\$1.99	60%
Selepen	\$18.24	\$29.93	\$11.68	64%
Sodium Acetate	\$8.81	\$14.63	\$5.82	66%
Sodium Bicarbonate	\$2.04	\$3.33	\$1.29	63%
Sodium Chloride	\$.68	\$1.40	\$.72	106%
Sodium Phosphate	\$5.81	\$9.08	\$3.27	56%
Tracelyte	\$8.26	\$11.57	\$3.31	40%
Vinblastine Sulfate	\$26.50	\$43.23	\$16.73	63%
Water for Injection	\$1.10	\$2.34	\$1.24	113%

363. As set forth above, Fujisawa's scheme to inflate its reported AWPs and market the resulting spread to increase the market share of its drugs has resulted in excessive overpayments by Plaintiffs and the Class.

#### **J. The GSK Group (GlaxoSmithKline, SmithKline Beecham, Glaxo Wellcome)**

364. The GSK Group has engaged in an organization-wide and deliberate scheme to inflate AWPs. The GSK Group has stated fraudulent AWPs for all or almost all of its drugs, including those set forth below. The specific drugs manufactured and/or distributed by the GSK Group for which relief is sought in this case are set forth in Appendix A and are identified below:

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
GSK GROUP (SmithKline	Advair Diskus	salmeterol-fluticasone	Bronchodilator (Respiratory Agent) Used for treatment of asthma
Beecham, GlaxoSmithKline and Glaxo Wellcome)	Agenerase	amprenavir	Antiviral Agent Used in treatment of HIV infection
	Alkeran	melphalan	Antineoplastic Used to treat ovarian cancer and a certain type of cancer in the bone marrow

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
	Amerge	naratriptan succinate	Antimigraine Agent Used for treatment of migraine attacks
	Beconase AQ	beclomethasone dipropionate monohydrate	Anti-Inflammatory Agent Used to treat discomfort of hay fever, other allergies, and other nasal problems
	Ceftin	cefuroxime axetil	Antibacterial Agent Used to treat infections caused by bacteria
	Combivir	lamivudine-zidovudine	Antiviral Agent Used in treatment of HIV infection
	Daraprim	pyrimethamine	Antiprotozoal Used for treatment of malaria and other protozoal infections
	Epivir	lamivudine	Antiviral Agent Used in treatment of HIV infection
	Flonase	fluticasone propionate (nasal)	Anti-Inflammatory Agent Used for treatment of allergic and nonallergic rhinitis
	Flovent	fluticasone propionate (inh)	Antiasthmatic (Anti-Inflammatory Agent) Used for treatment of asthma
	Imitrex	sumatriptan or sumatriptan succinate	Antimigraine Agent Used for treatment of migraine attacks or cluster headaches
	Kytril	granisetron hcl	Antiemetic (Gastrointestinal Agent) Used to prevent the nausea and vomiting that may occur after chemotherapy
	Lamictal	lamotrigine	Anticonvulsant Used to help control some types of seizures in the treatment of epilepsy
	Lanoxin	digoxin	Antiarrhythmic Agent (Cardiovascular Agent) Used to improve the strength and efficiency of the heart, or to control the rate and rhythm of the heartbeat.
	Leukeran	chlorambucil	Alkylating Agent (Antineoplastic) Used to treat cancer of the blood and lymph system
	Mepron	atovaquone	Antiprotozoal Used to treat and to prevent pneumonia
	Myleran	busulfan	Antineoplastic Used to treat some kinds of cancer of the blood.
	Navelbine	vinorelbine tartrate	Antineoplastic Used for treatment of lung cancer

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
	Paxil	paroxetine hcl	Antianxiety agent; Antidepressant (Psychotherapeutic Agent) Used in the treatment of various psychotherapeutic disorders
	Purinethol	mercaptopurine	Antimetabolite (Antineoplastic) Used to treat some kinds of cancer.
	Relenza	zanamivir	Antiviral Agent Used in the treatment of the infection caused by the flu virus (influenza A and influenza B).
	Retrovir	zidovudine	Antiviral Agent Used for treatment of HIV infection
	Serevent	salmeterol xinofoate	Bronchodilator (Respiratory Agent) Used to treat or prevent symptoms of asthma, chronic bronchitis, emphysema, and other lung diseases
	Trizivir	abacavir sulfate-lamivudine-zidovudine	Antiviral Agent Used for treatment of HIV-1 infection
	Valtrex	valacyclovir hcl	Antiviral Agent Used for treatment of shingles and genital herpes
	Ventolin HFA	albuterol sulfate	Bronchodilator (Respiratory Agent) Used for treatment or prevention of bronchospasm
	Wellbutrin	bupropion hcl	Antidepressant (Psychotherapeutic Agent) Used for treatment of depression
	Zantac	ranitidine hydrochloride	Gastrointestinal Agent Used in the treatment of active duodenal ulcer
	Ziagen	abacavir sulfate	Anti Infective Agent Used in the treatment of HIV infection
	Zofran	ondansetron hcl	Antiemetic (Gastrointestinal Agent) Used to treat or prevent the nausea and vomiting that may occur after chemotherapy
	Zofran ODT	ondansetron	Antiemetic (Gastrointestinal Agent) Used to treat or prevent the nausea and vomiting that may occur after chemotherapy
	Zovirax	acyclovir	Antiviral Agent Used for treatment of shingles, genital herpes and herpes simplex
	Zyban	buproprion hcl	Antidepressant (Psychotherapeutic Agent) Used to relieve mental depression. Also used to aid in cessation of smoking
		thioguanine	Antineoplastic Used to treat some kinds of cancer

**1. The GSK Group Has Been the Target of Government Investigations**

365. In connection with its scheme to inflate AWPs, the GSK Group has been investigated by the United States Department of Justice, the Office of Inspector General of the Department of Health and Human Services, the Attorney General for the State of Texas, the Attorney General for the State of California, and the Attorney General for the State of Nevada, Medicaid Fraud Control Unit.

366. These investigations confirm that the GSK Group has engaged in a deliberate scheme to inflate the published AWPs for its drugs.

**2. The GSK Group's Definition and Understanding of AWP**

367. In a GSK document entitled "Zofran Tablets & Zofran Injection: Sales Training Guide Reimbursement Module" (GSK-MDL-ZN02-035925) (Highly Confidential), GSK defines AWP as follows:

Average Wholesale Price (AWP): The composite wholesale prices charged on a specific commodity that is assigned by the drug manufacturer and is listed in either the Red Book or Blue Book and used by third-party payers as a basis for reimbursement.

(GSK-MDL-ZN02-035985) (Highly Confidential). Thus, by its own definition, GSK recognizes that: (i) AWP should be an average of actual wholesale prices; (ii) the drug manufacturers control the published AWP; and (iii) the published AWPs directly affect the payments made by the Class.

**3. The GSK Group Controls the Published AWP for Its Products**

368. The GSK Group has controlled and set the AWPs for its pharmaceutical products during the Class Period. As set forth below, any claim that The GSK Group only reports a WAC to industry compendia and therefore is not responsible for the published AWPs is belied by its own documents. For example:

a. In 1991 a Glaxo document entitled "Zofran Third Party Payment Plan," among the many recommendations concerning the pricing of its then new drug Zofran was the

recommendation that “In establishing direct-to-wholesaler and *Red Book* wholesale prices for Zofran, Glaxo should take into consideration physicians’ expected profit margins.” (GSK-MDL-ZN02-03428) (Highly Confidential).

b. Expanding further on the recommendation above, elsewhere in the same document it is stated: “Because insurers often reimburse physician-infused drugs up to the average wholesale price (AWP), the doctor’s profits are determined by the differential between the AWP and the price they pay to the wholesaler or pharmacy supplier. The company should ensure that doctors will make acceptable return on Zofran® by managing markups through the distribution chain.” (GSK-MDL-ZN02-034366) (Highly Confidential).

369. As do all of the Defendants, GSK has direct control over the “markups” in the distribution chain for its products. That control results from an ability to set the published AWP.

**4. The GSK Group’s AWP Manipulation Benefited Providers at the Expense of Plaintiffs and the Class**

370. GSK acknowledged that the AWP, as published in industry compendia, was used as the basis for most payments by third party payors. GSK’s own documents state, “Most, but not all, plans determine a payment for new drugs, based on the drug’s cost as listed in the *Red Book* and pay all providers that amount less any patient co-payments.” (GSK-MDL-ZN02-035965) (Highly Confidential). Elsewhere in the same document GSK acknowledges: “Payment amounts for most payers is usually based on the AWP as listed in *Red Book*, however, co-payments, especially for Zofran Tablets will be required.” (GSK-MDL-ZN02-035973) (Highly Confidential).

371. The purpose of The GSK Group’s AWP manipulation was to increase the spread in order to maximize the profit to providers and other intermediaries at the expense of Plaintiffs and the Class. That scheme has resulted in a system where drugs are administered based upon a profit incentive to physicians and other intermediaries and which results in an incentive to prescribe more expensive, rather than cheaper drugs. In talking points prepared in advance of

negotiations with clinics, Glaxo instructed its sales people to remind customers that “Cheaper is not necessarily a prudent medical or business decision” and that “Cheaper ≠ Good medicine or Good Business!” (GSK-MDL-ZN02-077818-19) (Highly Confidential).

372. The GSK Group tried to maximize spread because it understood that its customers routinely engaged in “spread shopping” – comparing its AWPs with those of its competitors in order to determine the greatest spread (and therefore sell or administer the drug with the greatest spread).

373. Perhaps the most flagrant example of the GSK Group’s fraudulent manipulation of AWPs is found in the documents relating to Glaxo’s Zofran® and SKB’s Kytril®. These two drugs both minimize the nausea associated with chemotherapy, and, prior to the merger of Glaxo and SKB, competed head-to-head in the same market. As detailed below, much of that competition concerned which product could generate *the greater spread*, or profit, for physicians; not over which product was better for patients.

##### 5. Glaxo’s Zofran®

374. A Glaxo marketing document, sent to its sales and marketing personnel via U.S. Mail and interstate wire facilities, advises that they should emphasize to medical providers both the benefits of Zofran® and the financial benefits of the spread. Specifically:

By using a 32 mg bag, the physician provides the most effective dose to the patient and increases his or her profit by \$ \_\_\_\_\_ in reimbursement as well as paying no upcharges for the bag or admixing

375. A follow-up internal Glaxo memo, dated October 27, 1994, entitled “Zofran Pricing Recommendation,” states: “Physician reimbursement for the administration of intravenous oncology drugs is based on the spread between acquisition cost and the AWP.” The memo later notes that “Kytril carries a 20% spread between List Price and AWP compared to Zofran which carries a 16 2/3% spread providing SKB with a significant advantage in the clinic setting with respect to reimbursement.” (P007015-P007490, at P007487-P007490).

376. In response to the larger spread being offered on Kytril, this same internal document discusses several options to increase Zofran's spread "to balance the reimbursement spread which currently exists between Zofran and the market in which it competes. . ." The pricing options considered for increasing the "spread" for Zofran® included:

Recommendation #1

4.5% price increase	\$178.97 to \$187.02
Increase AWP	16 2/3% to 20% \$214.76 to \$233.78 (8.5%)
3%Wholesaler Rebate (11/14/94 - 1/31/95)	\$187.02 to \$172.92 (chargeback) \$179.92 to \$167.31 (rebate)

377. In an effort to hide the fact that Glaxo was increasing the spread for Zofran®, Glaxo elected to not only increase its AWP and provide rebates, but to also include a small actual price increase. In describing the reason for an increase in the actual selling price, an internal Glaxo document states:

The recommended multi-tiered modification to current promotion, should also provide an immediate resultant impact to weekly unit sales without being easily intelligible by SKB as to the means by which this was achieved. Thus, providing additional time before a competitive response would be delivered.

378. Glaxo internal documents, however, recognized that as a result of its increasing the spread for Zofran®, SKB would have two options:

Option 1: Decrease the purchase price of Kytril.

Option 2: Take a price increase to raise the AWP while maintaining purchase price to generate a higher spread than \$52.00.

(P007015-P007490, at P007489-P007490).

379. In order to increase the spread for Zofran®, Glaxo increased the AWP for a 20 ml injection of Zofran® to \$233.02 in January of 1995. This was discussed in an October 27, 1994

memo entitled "Zofran Pricing Recommendation" and further discussed at a Glaxo pricing committee meeting on November 4, 1994. (P007015-P007490, at P007487-P007490).

380. In February 1995, the *Florida Infusion Chemo Net* reported that Glaxo was increasing the published AWP for Zofran®, but was specifically offering incentives to lower the actual price offered to medical providers, thereby allowing medical providers to seek reimbursement at inflated prices. Specifically:

Effective January 3, 1995. Glaxo has increased the acquisition costs of Zofran injection. The new AWP is set at \$233.02. However, the company has provided incentives to the market place which will ensure that Zofran price to physicians and clinics will be lower than the contractual price available prior to the increase.

Letter from Bliley, Chairman Commerce Committee to Nancy Min DeParle, Sept. 25, 2000 (P007015-P007490, at P007046).

381. Glaxo was fully aware that the larger spread for its product would be a big selling point. A flier in GSK's possession but produced by wholesaler NSS advertises to physicians that:

Your Zofran™ Deal Just Got Better!!!

(Effective 4:00pm January 9, 1995)

\*New AWP \$233.02

New Price from NSS

\*\* \$161.00 \* \*

(GSK-MDL-ZN02-034942) (Highly Confidential).

382. In March 1996, Glaxo again increased the AWP for Zofran® by 4.8%. In response, SKB immediately increased the AWP for Kytril by 4.8%. An internal SKB memo, dated March 21, 1996, entitled "Kytril Price Increase," states:

I recommend a 4.8% price increase effective March 25, 1996 for all Kytril presentations. This is in response to a Glaxo Wellcome price increase of 4.8% for Zofran effective March 8, 1996.

(P007015-P007490, at P007078).

383. In a Glaxo internal memo dated October 25, 1994, entitled "Issue considerations on Zofran pricing strategies," Nancy Pekarek (a communications manager for Glaxo who later became Vice-President of U.S. Corporate Media Relations) recognized the implications of increasing the AWP to create a better spread:

If Glaxo chooses to increase the NWP and AWP for Zofran in order to increase the amount of Medicaid reimbursement for clinical oncology practices, we must prepare for the potential of a negative reaction from a number of quarters. Some likely responses:

(1) Press: Glaxo's health care reform messages stressed the importance of allowing the marketplace to moderate prices. On the surface, it seems that in response to the entrance of a competitor in the market, Glaxo has actually raised its price on Zofran—perhaps twice in one year. How do we explain that price increase on a drug that is already been cited in the press as one of, if not the most expensive drug on the hospital formulary?

*If we choose to explain the price increase by explaining the pricing strategy, which we have not done before, then we risk further charges that we are cost shifting to government in an attempt to retain market share.*

(2) Congress: Congress has paid a good deal of attention to pharmaceutical industry pricing practices and is likely to continue doing so in the next session. How do we explain to Congress an 8% increase in the NWP between January and November of 1994, if this policy is implemented this year? How do we explain a single 9% increase in the AWP? *What arguments can we make to explain to congressional watchdogs that we are cost-shifting at the expense of the government?* How will this new pricing structure compare with costs in other countries?

(3) *Private insurers, out-of-pocket payers: These groups, and perhaps others, are likely to incur greater costs as a result of this pricing strategy. How will they be affected? What response do we have for them?*

(GSK-MDL-Z01-05675) (Highly Confidential) (emphasis added).

384. Glaxo also knew that Zofran® products were being marketed based on the spread between the actual cost and the published AWP. For example, when Glaxo introduced the Zofran® premixed IV bag, it used marketing materials which stated:

Convenient  
Costs Less Than Vial  
Higher AWP  
Better Reimbursement

(P007015-007490, at P007243).

385. Other internal Glaxo documents directly compared the “Profit Per Dose” and “Profit as %” and “Profit Per Vial” of Zofran® to Kytril®. These comparisons also identified that in order to increase the spread for Zofran®, Glaxo included “early pay disc” and “rebates” and “incentive.”

386. In marketing the new Zofran® premixed IV bag, Glaxo produced and used a document entitled “Profit Maximization – It’s In the Bag.” This document compared Kytril® to Zofran® based upon its total return of investment (ROI). Specifically, Glaxo’s marketing materials including the following chart:

	Cost	AWP	Potential Reimbursement/ Patient	Reimbursement/ Year	ROI
Zofran 32mg bag	\$110.41	\$195.00	84.59	\$13,957,350	76.6%
Kytril 1 mg vial	\$102.73	\$175.00	72.27	\$11,924,000	70.3%

(P007114) (Highly Confidential).

387. Another Glaxo document entitled “Profit Maximization – Continued” reflects how much “Total Revenue Potential” there was for using Zofran® because of the large spread between the cost and reimbursement for various Zofran® products. (P007115) (Highly Confidential).

388. An internal SKB document further acknowledges Glaxo’s attempts to use and market the spread and its effects on the Class:

As of late, Glaxo promotional efforts have focused almost entirely on the financial benefits of “up-dosing” rather than efficacy of Zofran. *Though physicians have certainly benefited financially from such tactics, it is costing 3<sup>rd</sup> party payers and patients more for medication.*

(P007115-P007490, at P007138-P007139) (Highly Confidential) (emphasis added).

389. In a September 27, 2000 article in *USA Today*, Glaxo spokesman Rick Sluder (who received a copy of the October 24, 1994 memo described herein) discussed the issue of the spread and blamed a system that set up a reimbursement method that relies on average wholesale prices which are not actually “representative of actual prices.” Mr. Sluder, admitting that Glaxo changed its wholesale prices to keep up with competitors who changed wholesale prices, stated “We didn’t want to put ourselves at a price disadvantage.” Mr. Sluder also admitted that the marketing of Glaxo drugs is based, in part, on the spread. In fact, he noted that Glaxo’s sales staff is briefed on the price advantages to doctors who bill and get reimbursed based upon the AWP. (E-mail from Clapton to Vaughan dated Sept. 27, 2000 citing “How Drug Makers Influence Medicare Reimbursements to Doctors; WALL STREET JOURNAL (P007501-P007506).

## 6. SKB’s Kytril

390. According to its internal documents (and prior to selling Kytril®’s global rights to the Roche Group in December 2000), SKB also knew that by creating the spread for Kytril®, it could directly affect the amount of revenue medical providers receive and thereby affect overall demand for Kytril®. Specifically, an August 6, 1996 internal SKB memo stated:

In the clinic setting however, since Medicare reimbursement is based on AWP, product selection is largely based upon the spread between acquisition cost and AWP.

\* \* \*

From this analysis, there seems to be no other reason, other than profitability, to explain uptake differentials between the hospital and clinic settings, therefore explaining why physicians are willing to use more expensive drug regimens.

(P007015-P007490, at P007249-P007250).

391. Internal SKB documents reveal how it marketed the spread. One internal document entitled "Price Comparison of Kytril and Zofran for Reimbursement" discussed how much additional revenue and "spread per patient" a medical provider would make by using Kytril® due to its larger spread. It stated:

Kytril reimbursement for 5 patients treated \$540.00 - Kytril 6 treated patients \$423.12

Difference = \$117.00 every 6 patients.

Use 5ht3 5 times a day = \$2,340.00 month. \$28,080.00 year more!  
(P007015-P007490, at P007117).

392. Other internal SKB documents entitled "Cost v. Profit" and "Kytril Profit Model" compare Kytril® and Zofran® to demonstrate how much additional profit/revenue the medical provider will receive by using Kytril®.

#### **7. General Counsel Correspondence Between Glaxo and SKB**

393. Most revealing is an exchange of correspondence between counsel for Glaxo and SKB over Zofran® and Kytril® in which each accuse the other of fraud.

394. On February 6, 1995, Timothy D. Proctor, Senior Vice President, General Counsel and Secretary for Glaxo, sent a letter to J. Charles Wakerly, Senior Vice President, Director and General Counsel of SKB informing him of "several issues pertaining to the advertising and marketing of Kytril":

Glaxo's sales representatives have encountered a substantial amount of what appear to be "homemade" Kytril vs. Zofran cost comparisons. It is our understanding that many of these pieces have been generated through a company-provided lap top computer program.

. . . .

In addition, a significant number of these pieces (see Exhibits F-J) contain direct statements or make references as to how institutions can increase their "profits" from Medicare through the use of Kytril. Some even go so far as to recommend that the medical professional use one vial of Kytril for two patients (see Exhibit F)

but charge Medicaid for three vials. This raises significant fraud and abuse issues which I am sure you will want to investigate."

(P007015-P007490, at P007123-P007126).

395. On February 22, 1995, Ursualy B. Bartels, Vice President and Associate General Counsel for SKB, wrote in response that SKB was investigating Glaxo's claims and asked whether Glaxo had specific information regarding the improper marketing of Kytril. Mr. Bartels also accused Glaxo of using false and misleading marketing materials regarding Zofran that rely on the medical providers' ability to garner more profit. Specifically, he stated:

Regarding similar concerns, we would like to draw your attention to reports we are receiving from our field force regarding reimbursement issues. In an apparent effort to increase reimbursement to physicians and clinics, effective 1/10/95, Glaxo increased AWP for Zofran by 8.5%, while simultaneously fully discounting this increase to physicians. The latter was accomplished by a 14% rebate available to wholesalers on all non-hospital Zofran sales on the multi-dose vial. *The net effect of these adjustments is to increase the amount of reimbursement available to physicians from Medicare and other third party payors whose reimbursement is based on AWP.* Since the net price paid to Glaxo for the non-hospital sales of the Zofran multi-dose vial is actually lower, it does not appear that the increase in AWP was designed to increase revenue per unit to Glaxo. *Absent any other tenable explanation, this adjustment appears to reflect an intent to induce physicians to purchase Zofran based on the opportunity to receive increased reimbursement from Medicare and other third party payors. In fact, we have had numerous verbal reports from the field concerning Glaxo representatives who are now selling Zofran based on the opportunity for physicians to receive a higher reimbursement from Medicare and other third-party payors while the cost to the physician of Zofran has not changed.*

(P007015-007490, at P007478-P007481) (emphasis added).

396. On April 25, 1995, Adrianna L. Carter, Glaxo Assistant General Counsel, responded to SKB's February 22, 1995 letter. Ms. Carter provided, pursuant to SKB's request, numerous additional examples of false and misleading marketing materials concerning "cost comparisons distributed to health care professionals by SmithKline representatives." Ms. Carter also denied SKB's allegations regarding "fraud and abuse" over the price increase of Zofran.

However, Ms. Carter did admit that the AWP price increase for Zofran® does not affect the actual cost to medical providers and that Glaxo's sales representatives were using the "spread" to gain market share. Specifically, Ms. Carter stated:

It is true that, despite a price increase, some physicians and other healthcare professionals will not see the higher price as the result of rebates or other incentives.

\* \* \*

It is also true that our sales representatives have been explaining the relationship between the price and Medicare reimbursement for Zofran to physicians.

\* \* \*

Finally, Ms. Carter stated that despite SKB's assertions that any alleged improper marketing of Kytril would end, "Unfortunately, despite your efforts, these activities are still ongoing."

(P007015-007490, at P007127-P007131).

397. The fact that Glaxo and SKB each accused the other of similar conduct, but neither took any action to bring it to the attention of the public or the appropriate authorities, is evidence that each of them were engaged in an ongoing scheme to defraud the Plaintiffs and Class.

#### **8. Other Improper Incentives**

398. In addition to marketing the spread on its products, the GSK Group has also used other methods to induce physicians and other intermediaries to use its drugs such as rebates and free samples in order to increase the spread between acquisition costs and reimbursement.

399. In an e-mail by GSK account representative Paul J. Ostruszka explaining how he was able to increase the market share of Zofran over Anzimet, among the suggested techniques he recommends to his fellow GSK account reps is "Ask your customers how much JUST 1 FREE Zofran Tablet Sample is WORTH" (emphasis in original). This e-mail was later forwarded to the entire Zofran team. (GSK-MDL-ZN02-077634).

400. An advertisement in the *Florida Infusion Chemo net* reveals that SKB created the spread not only by artificially inflating the AWP for Kytril®, but also by providing discounts and rebates. Specifically, the advertisement states:

We have been notified that, effective April 1, 1995, SmithKline's long running promotional rebate for Kytril purchases will come to a very successful conclusion.

(P007015-007490, at P007187).

401. SKB also knew that medical providers were billing Plaintiffs and the Class for a 1 mg single dose vial per patient, but actually were using less than the full single dose per patient. Depending on the weight of a patient, medical providers were able to use less of the drug, *i.e.*, the lighter the patient, the less Kytril® was needed. SKB subsequently introduced a Kytril® 4 mg Multi-Dose vial that allowed medical providers to bill 6 treatments for the cost of 4. For example, an SKB marketing document entitled "Kytril Vial Usage" states, "You can use only three vials of Kytril for four patients." (P007015-007490, at P007068 and P007455).

402. SKB also used other financial incentives to decrease medical providers' costs and thereby increase profits. For example, SKB promised to contribute to research and education programs through the OnCare Foundation if OnCare agreed to use Kytril instead of a competing drug. (P007015-007490, at P007061).

## **9. Specific GSK Group AWPs Documented by the DOJ**

403. In a report published by the DHHS (the "DHHS Report"), the DOJ documented that the published AWPs for various dosages of Zofran and Kytril manufactured by The GSK Group were substantially higher than the actual prices listed by wholesalers. The chart below sets forth the AWPs identified by the DOJ and the spread associated with one particular dosage of each drug. These figures compare the DOJ's determination of an accurate AWP for that particular dosage, based upon wholesalers' price lists, with the AWP reported by The GSK Group in the 2001 *Red Book*.

<b>Drug</b>	<b>GSK 2001 <i>Red Book</i> AWP</b>	<b>DOJ Determined Actual AWP</b>	<b>Difference</b>	<b>Percentage Spread</b>
Ondanestron (Zofran)	\$128.24	\$22.61	\$101.63	450%
Granisetron (Kytril)	\$195.20	\$139.04	56.16	40%

(P006299-P006316).

404. As set forth above, the GSK Group's scheme to inflate its reported AWPs and market the resulting spread to increase the market share of its drugs has resulted in excessive overpayments by Plaintiffs and the Class.

#### **K. Immunex**

405. Immunex engages in an organization-wide and deliberate scheme to inflate AWPs. Immunex has stated fraudulent AWPs for all or almost all of its drugs, including those set forth below. The specific drugs of Immunex for which relief is sought in this case are set forth in Appendix A and are identified below:

<b>Manufacturer</b>	<b>Brand Name (if applicable)</b>	<b>Generic Name</b>	<b>Therapeutic Category/Usage</b>
IMMUNEX	Leukine	sagamostin	Antineutropenic Agent Used to help produce bone marrow and white blood cells
	Novantrone	mitoxane hydrochloride	Antineoplastic Used in the treatment of multiple sclerosis and various forms of cancer
	Thioplex	lyophilized thiotepa	Antineoplastic Used in the treatment of ovarian and breast cancer, lymphoma and bladder tumors
		leucovorin calcium	Antianemic Agent (Blood Modifier) Used in the treatment of anemia
		methotrexate sodium	Antineoplastic Used in the treatment of various forms of cancer

#### **1. Immunex Has Been the Target of Government Investigations**

406. In connection with its scheme to inflate AWPs, Immunex has been investigated by the United States Department of Justice, the Office of Inspector General of the Department of

Health and Human Services, the Attorney General for the State of Texas, and the Attorney General for the State of California.

**2. Immunex Definition and Understanding of AWP**

407. Immunex's internal documents reveal that it understood how industry compendia defined and utilized AWPs:

Red Book Definition of AWP

The average wholesale price as we consider it here at Red Book is the price a retail hospital or pharmacy pays if purchases product from wholesaler before the discount if any.

Blue Book Definition of AWP

AWP represents an average price which a wholesaler would charge a pharmacy for a particular product.

(IAWP002238) (Highly Confidential).

**3. Immunex Controls the Published AWP for its Products**

408. Immunex controlled and set the AWPs for its pharmaceutical products through direct communications with industry compendia during the Class Period. In 2000, in the midst of numerous government investigations concerning AWP manipulation, Immunex denied responsibility for controlling the published AWP for its products. For example, in an October 26, 2000 letter to *Red Book*, Immunex states in pertinent part:

As requested, enclosed please find an updated summary of list pricing and package information for Immunex products. Please note that Immunex Corporation is not responsible for setting the Average Wholesale Price (AWP). Therefore, we do not set or approve AWP information for any Immunex products.

(IAWP023473) (Highly Confidential). Previously, in a 1996 interview, an Immunex spokesperson had informed Barron's that "drug manufacturers have no control over the AWPs published." (IAWP003071) (*Hooked on Drugs*, Barron's, Jun. 10, 1996).

409. Immunex's internal documents, however, establish that it controlled the AWP for all of its products throughout the Class Period. For example:

a. A January 12, 1996 letter from *Red Book* to Immunex, in pertinent part, states:

This letter is a confirmation letter that we have received and entered your latest AWP price changes in our system.

(IAWP008102) (Highly Confidential).

b. A January 12, 1995 letter from Immunex to *Red Book* states:

Below you will find a list of new suggested Average Wholesale Prices (AWPs) for selected Immunex products, along with a new NDC ... all effective January 10, 1995 ... Please update your databases accordingly. A new copy of Immunex's Average Wholesale Price Product Pricing Guide will be sent to you next week.

(IAWP016500) (Highly Confidential).

**4. Immunex's AWP Manipulation Benefited Providers at the Expense of the Class**

410. The purpose of Immunex's manipulation was to increase the spread in order to maximize the profit to providers and other intermediaries at the expense of Plaintiffs and the Class. Immunex understood that providers and intermediaries were reimbursed at AWP – and benefited from a larger spread.

a. In an internal document entitled "Health Care Policy Fast Facts," created in 1995, Immunex urged its sales personnel to remember "[p]hysician's offices use their own charge schedule for billing purposes, and get reimbursed at AWP, based on the published prices in the pricing databases." (IAWP012961) (Highly Confidential).

b. Recently, in a January 3, 2000 interoffice memo, Immunex discussed the significant revenues to be made by providers which used its Leucovorin and Methotrexate products. Specifically, Immunex stated that, "Leucovorin and Methotrexate represent significant revenue sources for the physician office or clinic. Due to the 'spread' (difference between

acquisition cost and AWP), physicians have reaped substantial profits.” (IAWP051149-52) (Highly Confidential).

411. Immunex, in a conscious effort to increase the spread for providers and intermediaries, changed its AWPs and marketing practices accordingly. In a February 21, 1997 internal memo discussing reimbursement on its products, in pertinent part, Immunex stated:

The following are the reimbursement schema for Leukine, Novantrone, Thioplex and Leucovorin:

Here’s the way it works [for Leukine] – the Red Book Price (AWP) for our 250 mcg is \$117.79 and \$221.71. **However**, payors take the \$117.79 and divide it by 5, now that we bill per 50 mcg increments. This is equal to \$23.56 per 50 mcg, hence reimbursement on a 500 mcg vial is \$235.60. We need to take into account that in some AOR markets they get AWP or AWP plus a percentage, in others, depending on the makeup of the patient population, they may only get the 80% Medicare allowable (\$188.48). So here’s what the spread looks like:

\$235.60 (AWP)	\$188.48 (80% Medicare allowable)
<del>-\$112.06 (AOR contract price)</del>	<del>-\$112.06</del>
+\$123.54 per 500 mcg vial (110% spread)	\$76.42 (68% spread)

(IAWP008528) (Highly Confidential) (emphasis in original).

412. Immunex performed an analysis of competitive AWP pricing (IAWP003407-13) (Highly Confidential) and established a “Reimbursement Hotline” for a number of its products (IAWP016686-88) (Highly Confidential).

413. Immunex, through its employees and agents, also provided free samples of its drugs to customers. (IAWP005418) (Highly Confidential) The free samples would be used to offset the total cost associated with purchases of its drugs, thereby increasing the spread, while also concealing the actual cost of the drug from Plaintiffs and the Class.

## 5. Specific Immunex AWPs Documented by the DOJ

414. In a report published by the DHHS (the “DHHS Report”), the DOJ documented at least 7 instances where the published AWPs for various dosages of 2 drugs manufactured by

Immunex were substantially higher than the actual prices listed by wholesalers. The chart below sets forth the 2 drugs identified by the DOJ and the spread associated with one particular dosage of each drug. These figures compare the DOJ's determination of an accurate AWP for that particular dosage, based upon wholesalers' price lists, with the AWP reported by Immunex in the 2001 *Red Book*.

<b>Drug</b>	<b>2001 <i>Red Book</i> AWP</b>	<b>DOJ Determined Actual AWP</b>	<b>Difference</b>	<b>Percentage Spread</b>
Leucovorin Calcium	\$137.94	\$14.58	\$123.36	846%
Methotrexate Sodium	\$20.48	\$7.10	\$13.38	188%

(P006299-P006316).

415. In a report published by DHHS in 1997, the Department undertook an analysis of the twenty drug codes that represented the largest dollar outlays to the Medicare Program and compared Medicare's payments with the prices available to the physician and supplier communities. For mitoxantrone hydrochloride, sold by Immunex under the brand name Novantrone, the DHHS found that Medicare paid \$172.81, while the actual average wholesale price was \$142.40, resulting in a spread of 21.36%. "Excessive Medicare Payments for Prescription Drugs" (Dec. 1997).

#### **6. Inflated AWPs From Immunex Price Lists**

416. In response to government subpoenas, Immunex produced numerous price lists setting forth spreads between AWPs and prices offered to wholesalers, providers and other intermediaries. A review of those price lists reveals that Immunex has consistently offered drugs and other solutions to its customers at prices significantly below the published AWP and that the spread was of great importance to its customers.

417. As set forth above, Immunex's scheme to inflate its reported AWPs and market the resulting spread to increase the market share of its drugs has resulted in excessive overpayments by Plaintiffs and the Class.

## 7. Immunex Concealed Its AWP Manipulation

418. Immunex deliberately acted to conceal its fraudulent reporting and marketing of the AWP spread. For example, under the guise of “simplifying” its product listings, on June 3, 1994, Immunex instructed the *Red Book* to “delete all references to Direct Price for all Immunex products, effective immediately” and confirmed that “only AWP (Average Wholesale Price) w[ould] be listed for [its] products[.]” (IAWP016524) (Highly Confidential). Immunex effectively hid the AWP spread from Plaintiffs and the Class.

## L. The Johnson & Johnson Group (J&J, Centocor and Ortho)

419. The Johnson & Johnson Group engages in an organization-wide and deliberate scheme to inflate AWPs. The Johnson & Johnson Group has stated fraudulent AWPs for all or almost all of its drugs, including those set forth below. The specific drugs of the Johnson & Johnson Group for which relief is sought in this case are set forth in Appendix A, and are set forth below:

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
JOHNSON & JOHNSON GROUP (J&J, Janssen, McNeil, Ortho and	Aciphex	rabeprazole sodium	Gastric Acid Pump Inhibitor (Gastrointestinal Agent) Used in the treatment of gastroesophageal reflux disease and duodenal ulcers
Centocor)	Bicitra	sodium citrate & citric acid	Alkalizer Used in the prevention of kidney stones
	Duragesic	fentanyl	Analgesic Used in the treatment of chronic pain
	Elmiron	pentosan polysulfate sodium	Anti-Inflammatory Agent Used for relief of pain associated with interstitial cystitis
	Erycette	erythromycin	Antiacne Agent; Antibacterial Agent Used to help control acne
	Flexeril	cyclobenzaprine	Skeletal Muscle Relaxant (Analgesic) Used in the treatment of muscle spasm associated with musculoskeletal conditions
	Floxin	ofloxacin	Antibacterial Agent Used in the treatment of pneumonia, bronchitis, gonorrhea and certain other infections

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
	Grifulvin	griseofulvin microsize	Antifungal Agent Used to treat fungus infections of the skin, hair, fingernails, and toenails
	Haldol	haloperidol lactate	Antiemetic (Gastrointestinal Agent); Antipsychotic (Psychotherapeutic Agent) Used to treat nervous, mental, and emotional conditions
	Haldol Decanoate	haloperidol decanoate	Antiemetic (Gastrointestinal Agent); Antipsychotic (Psychotherapeutic Agent) Used to treat nervous, mental, and emotional conditions
	Levaquin	levofloxacin	Antibacterial Agent Used to treat bacterial infections in many different parts of the body
	Monistat	miconazole nitrate	Antifungal Agent Used in the treatment of yeast infections
	Mycelex	clotrimazole	Antifungal Agent Used in the treatment of candidiasis and tinea versicolor
	Pancrease	amylase-lipase-protease	Digestant; Enzyme, Pancreatic (Gastrointestinal Agent) Used in the treatment of gastrointestinal orders
	Parafon Fort	chlorzoxazone	Skeletal Muscle Relaxant (Analgesic) Used to relax certain muscles and relieve the pain and discomfort caused by strains, sprains, or other injuries to muscles
	Polycitra	potassium & sodium citrates w/ citric acid	Alkalizer Used in the prevention of kidney stones
	Procrit	epoetin alfa	Antianemic Used in the treatment of anemia in HIV-infected, cancer or chronic renal failure patients
	Regranex	bevacizumab	Biological Response Modifier Used in the treatment of diabetic neuropathic ulcers
	Remicade	infliximab	Anti-Inflammatory Agent; Antirheumatic Agent Used to treat Crohn's disease and rheumatoid arthritis
	Reminyl	galantamine hydrobromide	Cholinesterase Inhibitor (Central Nervous System Agent) Used in the treatment of dementia of the Alzheimer's type

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
	Renova	tretinoin	Antiacne Agent Used for mitigation of fine wrinkles and other attributes of facial skin
	Retin-A	tretinoin	Antiacne Agent Used to treat acne
	Retin-A Micro	tretinoin microsphere	Antiacne Agent Used to treat acne
	Risperdal	risperidone	Antipsychotic Agent (Psychotherapeutic Agent) Used to treat the symptoms of psychotic disorders
	Spectazole	econazole nitrate	Antifungal Agent Used to treat infections caused by a fungus
	Sporanox	itraconazole	Antifungal Agent Used in the treatment of various fungal infections
	Terazol	terconazole vaginal	Antifungal Agent Used to treat yeast (fungus) infections of the vagina
	Testoderm	testosterone	Androgen; Antianemic Agent; Antineoplastic Used for replacement therapy in males with a deficiency or absence of testosterone
	Tolectin	tolmetin sodium	Antirheumatic Agent Used to relieve some symptoms caused by arthritis
	Topamax	topiramate	Anticonvulsant Used to help control some types of seizures in the treatment of epilepsy
	Tylox	acetaminophen w/ codeine	Analgesic Used to relieve pain.
	Tylenol with codeine		
	Ultracet	tramadol-acetaminophen	Analgesic Used to relieve pain
	Ultram	tramadol hcl	Analgesic Used for management of pain
	Urispas	flavoxate hydrochloride	Autonomic Nervous System Agent Used in the treatment of symptoms of various urologic disorders.
	Vascor	bepridil hcl	Antianginal Agent Used to relieve and control angina pectoris and hypertension

**1. The Johnson & Johnson Group Has Been the Target of Government Investigations**

420. In connection with its scheme to inflate AWPs, the Johnson & Johnson Group has been investigated by the General Accounting Office and the Office of the Attorney general for the Commonwealth of Massachusetts.

421. J&J's internal documents reveal that it was familiar with and understood how industry compendia defined and utilized AWPs. For example, in a rebate agreement between J&J and Merck-Medco Managed Care, Inc. dated December 19, 1996, the parties defined AWP as meaning "the average wholesale price as published in the most current version of either First Data Bank or the Red Book." (J&J000599) (Highly Confidential).

422. The Johnson & Johnson Group has engaged in an ongoing deliberate scheme to inflate AWPs and to market the spread to increase the sales of its products. In a report published by the GAO, federal investigations have documented fraudulently inflated AWPs reported for epoetin alpha (sold by J&J as Procrit). J&J is identified in various annual *Red Book* publications as one of two sources for epoetin alfa. The other source for epoetin alfa is Defendant Amgen.<sup>6</sup>

423. In September 2001, the GAO reported that epoetin alfa accounted for the second highest percentage of Medicare expenditures on drugs in 1999, accounting for 9.5% of spending for prescription drugs by Medicare in 1999 and for 3.4% of all Medicare allowed services. These massive federal expenditures for epoetin alfa, caused by the J&J Group and Amgen's AWP scheme as well as the inflated cost to Plaintiffs and members of the Class, are even more outrageous given the fact that the research and development of epoetin alpha was originally underwritten by grants from the federal government.<sup>7</sup>

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<sup>6</sup> Amgen markets epoetin alfa for use in the treatment of dialysis patients while the right to market epoetin alfa for all other uses is licensed to Defendant J&J.

<sup>7</sup> EpoGen® and Procrit® are based on different uses of a patented process technology developed at Columbia University with support from grants from the NIH. Columbia licensed their technology to Amgen for EpoGen® and to Johnson & Johnson for Procrit®. *NIH Response to the Conference Report Request for a Plan to Ensure Taxpayers' Interests are Protected*, Department Of Health And Human Services National Institutes Of Health, July 2001.